REMARKS

Applicant expresses appreciation to the Examiner for consideration of the subject patent application. This amendment is in response to the Office Action mailed July 9, 2010 in which each of pending claims 73-116 were rejected. Claims 73 and 116 have been amended to remove the term "prophylactically" from the claims. Claim 73 has further been amended to include the limitations of previously presented claims 90 and 91 and claims 90 and 91 have been canceled. Applicants submit that the present amendments are fully supported by the originally filed specification and that they do not introduce any new subject matter.

Claim Rejections - 35 U.S.C. § 112

Claim 73 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner has asserted that the specification fails to adequately enable the prophylactic use of the claimed substances. Without conceding the correctness of the Examiner's rejection, Applicants have amended the claims to remove all language regarding the prophylactic use of the claimed substances. Accordingly, Applicants submit that the rejection is rendered moot and request its withdrawal.

Claim Rejections - 35 U.S.C. § 103

Claims 73, 76-81, 89, 90-99, and 107-115 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application No. 2003/0170307 (hereinafter "Royer").

Before discussing the obviousness rejections herein, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. The Applicant does not deem it necessary to recite the entire case law standard required in order to establish a *prima facie* case of obviousness. However, the Applicant would like to briefly remind the Examiner that a *prima facie* case of obviousness generally includes establishing: 1) that the asserted references as modified or combined teach or suggest each and every element of the claimed invention, 2) that the asserted references as modified or combined provide a sufficient likelihood of successfully making the modification or

combination, and 3) a reason for the modification or combination asserted.

Additionally, under *KSR*, and as outlined under the MPEP § 2143, additional rationales include (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of known technique to improve similar devices (methods, or products) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) "obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. The Applicant respectfully asserts the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in any of the rejections.

First, Applicants note that claim 73 has been amended to include the limitations of previously presented claims 90 and 91, namely limitations regarding the amounts of expandable agent and sorbed aqueous medium that is present in the claimed composition. With regard to these claimed amounts, the Examiner has asserted that "it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the concentrations of the expandable agent and sorbed aqueous medium." The Applicant submits that MPEP 2144.05 II(B) addresses this issue, stating:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

In light of this explicit discussion in the MPEP, the Applicant contends that the Examiner has not shown that Royer taught or recognized the amount of expandable agent and the amount of sorbed aqueous medium to be result effective variables in the composition. In fact, Royer does not even use the term "expandable agent" or anything akin to such a term, but rather only coincidentally discloses in a single example a single compound (i.e. sodium bicarbonate) that falls within the scope of expanding agents claimed in the present invention. In fact, Royer does not even discuss or disclose the functionality or purpose of the sodium bicarbonate that is present in the example, let alone mention a specific reason for the amounts recited. In short, nothing in Royer supports the Examiner's allegation that the present ranges recited would be merely routine obvious optimization of the amounts of the compound. Applicants contend that optimization of the amount of expandable agent cannot be done when the role of the expandable agent is not even recognized. One of ordinary skill in the art cannot optimize a variable that they do not recognize as result effective. Ergo, one of ordinary skill in the art would not be able to optimize the amount of an expandable agent when there is no recognition of the role of the expandable agent. The mere showing that a composition exists in the art that happens to disclose a compound that can be used, in the correct amounts, as an expandable agent is insufficient to constitute a recognition of the compound as a result effective variable. Thus it is evident that Examiner has used impermissible hindsight in constructing the present rejection. Thus, Applicants submit that the Examiner has not shown a *prima facie* case of obviousness with respect to the currently amended claims.

Further, Applicants note that the amount of expandable agent in the claimed compositions is an important feature that rises to the level of a result effective variable. Specifically, in order for the claimed compositions of the present invention to be commercially useful/viable, it is important for the claimed compositions to cure within a reasonable time period. When too much, e.g. more than 10%, expandable agent is included the curing time for the compositions increases to a length of time that could render the composition less usable or otherwise narrow its range of use. Delayed curing times can allow the composition to be displaced in or from a subjects tissue and can result in ineffective or improper delivery of the active agent. Additionally, prolonged cure times make patient compliance difficult because it is undesirable to limit movement for long periods of time.

For all of the foregoing reasons, Applicants submit that no *prima facie* case of obviousness has been established with respect to the pending claims. Therefore, Applicants respectfully request withdrawal of the rejection.

Claims 74 and 75 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Royer in view of U.S. Patent No. 5,162,117 (hereinafter "Stupak"). First, Applicants renew their arguments set forth above with respect to the failure to establish a *prima facie* case of obviousness over claim 73. Further, Applicants submit that nothing in Stupak or Royer teaches or suggests anything that would motivate one of ordinary skill in the art to deliver the active agents taught by Stupak as being deliverable orally in a composition intended for use in repairing periodontal defects, orthopedic defects, root canals, extraction sockets, and screw channels. Thus, Applicants submit that no *prima facie* case of obviousness has been established with respect to claims 74 and 75 and they respectfully request withdrawal of the rejection.

Claims 100-106 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Royer in view of U.S. Patent Application No. 2003/0158598 (hereinafter "Ashton"). First, Applicants renew their arguments set forth above with respect to the failure to establish a *prima facie* case of obviousness over claim 73. Further, Applicants note that although Ashton teaches pore sealing agents, such agents are taught for use in sealing the pores of medical devices such as stents and not for use in pharmaceutical compositions. Accordingly, Applicants submit that one of ordinary skill in the art would not logically combine the teachings of Ashton with Royer in order to arrive at the claimed invention. Further, Applicants note that Example 15 of Royer, the only example that teaches a compound that could be construed as an expandable agent, expressly teaches that the role of the composition is to form "porous orthopedic filler" and that the porosity of the composition "allows the penetration of cells." Thus, Applicants submit that even assuming, *arguendo*, that Ashton and Royer are sufficiently close in their field of art that one of ordinary skill might look to Ashton, such a person would not be inclined to combine the teachings of Ashton with Example 15 of Royer because such a combination would inherently destroy the functionality of the composition of Example 15. Inherently the role of a pore sealing agent is to seal the pores in a material, while the purpose of Royer's Example 15 is to produce a "Porous

Orthopedic Filler" that "allows the penetration of cells." Thus, a combination of the two would result in a composition that had clogged or sealed pores that would not allow for the desired passage of cells, thereby destroying the functionality of Royer's composition. Accordingly, for all of the foregoing reasons, Applicants submit that no *prima facie* case of obviousness has been established. Withdrawal of the rejection is requested.

CONCLUSION

In light of the above, Applicant respectfully submits that pending claims 73-89 and 92-116 are now in condition for allowance. Therefore, Applicant requests that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Amendment, the Examiner is strongly to call the undersigned attorney at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 20-0100.

DATED this 9th day of November, 2010.

Respectfully submitted,

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